

REMARKS

Applicants have amended Claims 1-13 and have added new Claim 26. Claims 14-25 have been withdrawn from consideration pursuant to a restriction requirement. Accordingly, Claims 1-13 and 26 are currently pending. Favorable consideration of the currently pending claims is respectfully requested in light of these amendments and the following remarks.

Restriction Requirement

Applicants note that the non-elected species and non-elected process claims may be rejoined if an elected species or product claim is found to be allowable.

Objections to the claims

In the Office Action mailed December 19, 2003, the Examiner objected to Claims 3, 4 and 11 as containing informalities. Applicants have amended these claims as requested by the Examiner to add the designation “(iii)” to Claim 11 and to remove the redundant use of the word “said” in Claims 3 and 4. Applicants respectfully submit that the amendments overcome the objections and request that they be withdrawn.

Rejection of claims under 35 U.S.C. § 112, second paragraph

The Examiner rejected Claims 1-13 as indefinite. Applicants have amended the Claims to remove the terms “capable”, “suitable”, “adapted for” and “such as”. Applicants have also amended Claim 13 to more precisely refer to a second adjuvant. Accordingly, Applicants respectfully submit that the amendments overcome the rejections and request that they be withdrawn.

Rejection of claims under 35 U.S.C. § 102(b) and 103(a)

The Examiner rejected Claims 1-9 and 11-13 as anticipated by, or in the alternative, as obvious over Duncan, D. *et al.* (International Application WO 94/20070). The Examiner stated that the Duncan *et al.* reference teaches a biologically active agent, an adjuvant chemical, i.e., Pluronic® block copolymers, polycations such as DEAE-4 and polyarnithine and an acceptable carrier. Applicants traverse the rejection as follows.

Applicants have amended Claim 1, section (ii)(A), to recite polyornithine as already recited in Claim 4. This amendment excludes polyarnithine from the amended claims. Applicant submits that it would non-obvious to substitute polyornithine for polyarnithine based upon a reading of the Duncan *et al.* reference because Duncan *et al.* select polyarnithine as a result of it being one of the possible “polycations.” Polyornithine is not cationic in nature and, therefore, would not be an obvious replacement in this context. A skilled person, told that a polycation is required, may look for other polycations, but would not consider polyornithine. Accordingly, Applicants submit that the teaching of polyarnithine in the Duncan *et al.* reference in no way anticipates or renders obvious the present claims.

With regard to amended Claim 1, section (ii)(B), the claim has been amended to clarify that the vitamin derivative is water soluble. Support for the amended claim can be found on at least page 7, lines 19-25 of the specification. This amendment makes clear that Claim 1 does not encompass vitamin A.

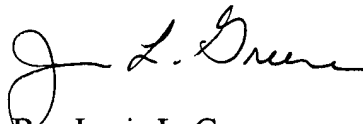
Furthermore, with regard to amended Claim 1, section (ii)(C), the claim has been amended to further define the composition as a positively charged cationic block copolymer or positively charged cationic surfactant. Support for the amendment can be found on at least page 6, lines 4-5 of the specification. Applicants respectfully submit that the range of Pluronic® block copolymers suggested in the Duncan *et al.* reference do not include positively charged cationic block copolymers or surfactants as required by the amended claims. The block copolymers suggested in the Duncan *et al.* reference are those produced by the Pluronic® trademark owner, BASF, and are non-ionic in nature as is shown in the attached information downloaded from the BASF website and extracts from the Condensed Chemical Dictionary and Surfactant Systems. Applicants submit that it would not have been obvious to substitute a positively charged block copolymer as required by the present claims, and including the ICI block copolymer, P101 and P121 copolymers, for the non-ionic block copolymers taught by Duncan *et al.* (The similarity in reference numbers to the BASF Pluronic® L-121 mentioned in the Duncan *et al.* reference and P121 of ICI mentioned on page 6, line 8 of the present specification is purely coincidental and does not indicate a similarity in their ionic nature.) Accordingly, Applicants submit that the teaching of Pluronic® in the Duncan *et al.* reference in no way anticipates or renders obvious the claims of the present application.

The Examiner further noted that the Duncan *et al.* reference teaches the use of “polycations such as DEAE-4 dextran and polyarnithine.” Applicants submit that these teachings in no way render the presently claimed invention anticipated or obvious since neither of these are block copolymers nor surfactants and do not fall within the terms of Claim 1(ii)(C). Polyarnithine also no longer falls within the limitations of Claim 1(ii)(A). Applicants further submit that it could not be predicted with any reasonable degree of certainty that DEAE-4 dextran and polyarnithine would have adjuvant properties based upon the teachings of the Duncan *et al.* reference. Accordingly, Applicants submit that the presently claimed invention is neither anticipated nor rendered obvious by the Duncan *et al.* reference. Applicants request that the Examiner review and withdraw these rejections.

Conclusions

Applicants are of the opinion that the above remarks are fully responsive to the Office Action mailed December 19, 2003 and that at least Claims 1-13 and 26 are now in condition for allowance. Such action is respectfully requested. No fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855. If there are informalities remaining in the application which may be corrected by Examiner's Amendment, or there are any other issues which can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 745-2517 is respectfully solicited.

Respectfully submitted,



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